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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/805,652
Filing Date: March 13, 2001
Appellant(s): SIRIMANNE ET AL.

WELSH & FLAXMAN, LLC
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 19, 2010 appealing from the Office action mailed November 17, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-7,16,17,22-24,31,33,34,111,122,123.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 1-7,16,17,22-24,31,33,34,111,122,123 under 35 USC 112, second paragraph.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2002/0012652	LEVY et al	1-2002
6,197,324	CRITTENDEN	3-2001
6,666,811	GOOD	12-2003
5,632,775	SUDING et al	5-1997
6,106,473	VIOLANTE et al	8-2000
4,985,019	MICHELSON	1-1991

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-7, 16, 17, 22-24, 31,33, 34,111,122,123 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, fails to disclose a cavity marking device

having at least two bodies made from different materials which are each detectable by non-invasive techniques. The specification discloses that the marker can be made from materials which are detectable by non-invasive techniques and that the body be made from materials which are detectable by non-invasive techniques. Paragraph 0057 of the specification (which is referred to by the appellant as having support for both implantable bodies being detectable) discloses "Also, the body itself may be adapted to have radiopaque, echogenic, or other characteristics that allow the body to be located by non-invasive technique without the use of a marker". The Examiner interprets this language as disclosing if a detectable marker is not used then the body can be made detectable. Therefore the specification provides support for either the body to be detectable or the marker to be detectable but both the body and marker would not be made detectable in a single device.

Claims 1-7, 16,31,33,34,111,122 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al (2002/0012652) in view of Crittenden (6,197,324). Levy et al disclose a bioactive agent in a microsphere. The term "bio-active agent" can include any substance that interacts with biological elements. The agent can include substances, such as dyes, to facilitate visualization of biological structures (para 0055). The microspheres can be used in combination with a biocompatible matrix that is implanted into a patient (para 0102). The matrix can also be surgically placed at the site of a wound (para 0104). The matrix can be formed from both natural and synthetic material, be biodegradable or non-biodegradable (where it is desired to leave

permanent structures in the body para 0103). With respect to claim 2, the non-biodegradable permanent matrix would inherently be non-bioabsorbable. Levy et al disclose that a biodegradable matrix is capable of being reabsorbed into the body. The matrix may take the form of a sponge or an implant, or gel (para 0103). The microspheres are then disposed within the matrix. Levy et al fail to disclose that both implantable bodies are detectable via non-invasive techniques. Crittenden discloses the use of a radiopaque marker in a pellet in order to show that its location can be properly determined. It would have been obvious to one skilled in the art to have modified Levy et al such that the first and/or second bodies includes a radiopaque material to ensure that the matrix/microsphere can be properly located using x-ray. Such a modification would allow the device to be used with a well known type of imaging modality that can be used to ensure its proper placement in the patient. With respect to claim 5, Levy et al disclose that any matrix polymer can be used (para 0103). With respect to claims 3, 6, the materials set forth are well known radiopaque materials and the selection of one would have been obvious based upon suitability for intended use. With respect to claim 16, Levy et al disclose implantation of the matrix at the site of a wound and it is a well known expedient in the art to provide a pain killing substance in combination with a medical procedure so as to reduce the pain that the implantation can cause. With respect to claim 31 the shape of the implant would have been an obvious design choice in the absence of any showing of criticality or unexpected result. With respect to claims 33, 34,111,122, the use of a sponge would include pores that allow tissue growth and an expandable body. It should be noted that the intended use of the

device as set forth in the claims is not given patentable weight. The modified device of Levy et al is capable of functioning as a subcutaneous cavity marking device in that the matrix can be implanted.

Claim 17 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al (2002/0012652)in view of Crittenden (6,197,324 as applied to claim 1 above, and further in view of Good (6,666,811). Levy et al disclose that the matrix can be implanted at a site of a wound. Good discloses an implantable body including a hemostatic material enabling it to be easily implanted in the tissue. It would have been obvious to one skilled in the art to have further modified Levy et al such that it includes a hemostatic material which enhances its ability to be implanted in the body.

Claims 22-23,123 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al (2002/0012652)in view of Crittenden (6,197,324 as applied to claim 1 above, and further in view of and Suding et al (5,632,775) or Michelson (4,985,019). Suding et al and Michelson each disclose the use of radiopaque patterns so that an element can be properly located using x-ray imaging. It would have been obvious to one skilled in the art to have further modified Levy et al such that the first and/or second bodies includes a radiopaque material where the material is arranged in a pre-defined pattern to ensure that the matrix/microsphere can be properly located using x-ray. Such a modification would allow the device to be used with a well known type of imaging modality that can be used to ensure its proper placement in the patient.

Claim 24 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al (2002/0012652) in view of Crittenden (6,197,324 as applied to claim 1 above, and further in view of Violante et al (6,106,473) and Suding et al (5,632,775) or Michelson (4,985,019). Levy et al fails to disclose the use of materials that are detectable using ultrasound and arranged with a pattern. Violante et al disclose the use of echogenic coatings that can be applied to pellets or implants to allow them to be visualized using ultrasound imaging. The coatings can be applied to capsules. Suding et al and Michelson each disclose the use of detectable patterns so that an element can be properly located using imaging. It would have been obvious to one skilled in the art to have further modified Levy et al such that the first and/or second bodies includes an ultrasound material where the material is arranged in a pre-defined pattern to ensure that the matrix/microsphere can be properly located using ultrasound. Such a modification would ensure that the matrix/microspheres are properly positioned in the patient.

(10) Response to Argument

With respect to Appellant's arguments regarding the rejection of claims under 35 USC 112, first paragraph, it is respectfully submitted that the specification discloses that either of the two implantable bodies can be detectable via a non-invasive technique but fails to disclose both being detectable in a single device. The disclosure on page 14 of the specification, paragraph 0057 refers to the body being detectable without the use of a marker. The Appellant's interpretation of this language as defining body the marker and body as being made from a detectable material is improper. The language clearly

implies that if a marker can be used as the detected material, one could make the body detectable.

With respect to the Appellant's arguments that the Examiner dismissed the preamble of the claims when interpreting the claim language, it is respectfully submitted that the Examiner did consider such language as limiting as far as whether or not the modified device of Levy et al would be capable of functioning as an implantable subcutaneous cavity marking device. The device of Levy et al is disclosed as being implanted into a body at a site such as a wound and therefore would be capable of functioning as a subcutaneous cavity marking device. It should be noted that while Levy et al is not directed to being used as a marking device, such omission fails to preclude it from being capable of functioning as such.

With respect to the argument that Levy et al fails to disclose visualization of the device, the use of the dye to allow visualization of biological structures would inherently allow the matrix/microspheres to also be visualized. Furthermore, it is a well known expedient, as evidenced by Crittenden, to provide materials to allow an implanted device or any portion of it to be visualized in order to ensure proper placement of such in the body.

With respect to Appellant's arguments that there is no need to visualize the microspheres in Levy et al, it is respectfully submitted that it is a well known expedient, as evidenced by Crittenden, to provide materials to allow an implanted device or any portion of it to be visualized in order to ensure proper placement of such in the body.

With respect to claim 2 and Appellant's arguments that Levy et al only teaches temporary markers, it is respectfully submitted that Levy et al disclose the use of permanent markers (para 0103).

With respect to claim 5 and Appellant argument's, while Levy et al fails to show both a polymer and a radiopaque additive, it is respectfully submitted that Levy et al disclose the use of a polymer (para 0103) and the combination of such with the teachings of Crittenden would provide the structure set forth in claim 5.

With respect to claim 16 and Appellant's arguments, Levy et al disclose implantation of the matrix at the site of a wound and it is a well known expedient in the art to provide a pain killing substance in combination with a medical procedure so as to reduce the pain that the implantation can cause. Therefore the use of a painkilling substance at the site of a wound, which is known to be painful, would have been obvious to one skilled in the art.

With respect to claim 31 and Appellant's arguments, while Levy et al may disclose the use of microspheres having certain diameter ranges, it should be noted that the microspheres would not be perfectly round and would include some degree of irregularity, furthermore, the Appellant has failed to provide any criticality in the specific shape of the implantable bodies and the exact shape chosen would have been an obvious design choice of known equivalents resulting in no significant difference from one obtained using the microspheres of Levy et al.

With respect to claim 17 and Appellant's arguments, the arguments are not understood in that Levy et al clearly disclose, in at least para 0102 and 0103, that the

matrix/microspheres are implanted. Therefore, in view of the teachings of Good, which discloses an implantable body including a hemostatic material enabling it to be easily implanted in the tissue, it would have been obvious to one skilled in the art to have modified Levy et al such that it includes a hemostatic material which enhances its ability to be implanted in the body.

With respect to claims 22,23,123 and Appellant's arguments, it is a well known expedient in the art to provide specific patterns that can clearly be seen using imaging techniques in order to properly locate an element in the body. Suding et al and Michelson each disclose the use of radiopaque patterns so that an element can be properly located using x-ray imaging. Therefore, it would have been obvious to one skilled in the art to have further modified Levy et al such that the first and/or second bodies includes a radiopaque material where the material is arranged in a pre-defined pattern to ensure that the matrix/microsphere can be properly located using x-ray. Such a modification would allow the device to be used with a well known type of imaging modality that can be used to ensure its proper placement in the patient. The Appellant only argues that the use of such a pattern using the microspheres would not be possible, given their size, however, the matrix itself could include such a material and would not be too small to show such a pattern under imaging.

With respect to claim 24 and Appellant's arguments, while Levy et al fails to specifically disclose locating the matrix when in the patient's body, it is a well known expedient in the art to locate an implantable body. Furthermore, Violante et al disclose the use of echogenic coatings that can be applied to pellets or implants to allow them to

be visualized using ultrasound imaging. The coatings can be applied to capsules. Suding et al and Michelson each disclose the use of detectable patterns so that an element can be properly located using imaging. Therefore, it would have been obvious to one skilled in the art to have further modified Levy et al such that the first and/or second bodies includes an ultrasound material where the material is arranged in a pre-defined pattern to ensure that the matrix/microsphere can be properly located using ultrasound. Such a modification would ensure that the matrix/microspheres are properly positioned in the patient. Again it should be noted that the Appellant only argues that it would not have been obvious to mark and/or locate the microspheres, however, the matrix itself could include such a material and would not be too small to show such a pattern under ultrasonic imaging.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ruth S. Smith/
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